

Sylvant (siltuximab)

SYLVANT is an interleukin-6 (IL-6) antagonist indicated for the treatment of patients with Multicentric Castleman's Disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

I. Criteria for Initial Approval

Sylvant will be considered for coverage when **all** of the criteria below are met, confirmed with supporting medical documentation.

- Patient is 18 years of age and older.
- Sylvant will be used as a single agent.
- Documented diagnosis of Multicentric Castleman Disease in patients who are both HIV and HHV-8 negative.
- Patient is currently free of all clinically significant infections and does not have evidence of organ failure.
- Documentation of Complete Blood Count (CBC) testing that documents all of the following, prior to the first siltuximab (Sylvant) dose:
 - Absolute neutrophil count greater than or equal to $1.0 \times 10^9/L$;
 - Platelet count greater than or equal to $75 \times 10^9/L$; and
 - Hemoglobin that is less than or equal to 17g/dL.
- Patients will NOT receive any live vaccines while being treated with Sylvant.
- Female patients must be advised of reproductive potential and counseled on the use of effective contraception during treatment with Sylvant and for 3 months after the last dose.

II. Criteria for Continuation of Therapy

All of the criteria for initial therapy (in **Section I.**) must be met; **AND** The provider must attest to a positive clinical response and absence of toxicity from the drug.

- Tumor response with stabilization or disease or decrease in size of tumor or tumor spread; AND
- Absence of unacceptable toxicity from the drug.

III. Dosing/Administration

Sylvant must be administered according to the current FDA labeling guidelines for dosage and timing. The recommended dosing is as follows:

- For intravenous infusion only - Administer as an 11 mg/kg dose given over 1 hour by intravenous infusion every 3 weeks.

IV. Length of Authorization for Therapy

Sylvant will be authorized for 6 months when criteria for initial approval are met. Continuing therapy with Sylvant will be authorized for 12 months.

V. Billing Code/Information

J2860 - Injection, siltuximab, 10 mg; 10 mg = 1 billable unit

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 2/23/2021

Last Reviewed Date: 2/23/2021